



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. FDA-2015-F-0714]

Natural Resources Defense Council et al.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by the Natural Resources Defense Council, the Center for Food Safety, the Breast Cancer Fund, the Center for Environmental Health, Clean Water Action, the Center for Science in the Public Interest, Children's Environmental Health Network, Environmental Working Group, and Improving Kids' Environment, proposing that we amend our food additive regulation to no longer provide for the use of three specific perfluoroalkyl ethyl containing food-contact substances (FCSs) as oil and water repellants for paper and paperboard for use in contact with aqueous and fatty foods.

DATES: The food additive petition was filed on January 7, 2015.

FOR FURTHER INFORMATION CONTACT: Paul Honigfort, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1206.

SUPPLEMENTARY INFORMATION:

## I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 4B4809), submitted by the Natural Resources Defense Council, 1152 15th St. NW., suite 300, Washington, DC 20005; the Center for Food Safety, 303 Sacramento St., Second Floor, San Francisco, CA 94111; Clean Water Action, 144 Eye St. NW., suite 400, Washington, DC 20005; the Center for Science in the Public Interest, 1220 L St. NW., suite 300, Washington, DC 20005; Children's Environmental Health Network, 110 Maryland Ave. NE., suite 402, Washington, DC 20002; the Breast Cancer Fund, 1388 Sutter St., suite 400, San Francisco, CA 94109-5400; the Center for Environmental Health, 2201 Broadway, suite 302, Oakland, CA, 94612; Environmental Working Group, 1436 U St. NW., suite 100, Washington, DC 20009; and Improving Kids' Environment, 1915 West 18th St., Indianapolis, IN 46202. The petition proposes that we amend § 176.170 (21 CFR 176.170) to no longer provide for the use of three perfluoroalkyl ethyl containing food-contact substances (FCSs) as oil and water repellants for paper and paperboard for use in contact with aqueous and fatty foods. The three FCSs which are the subjects of this petition are as follows:

1. Diethanolamine salts of mono- and bis (1H,1H,2H,2H perfluoroalkyl) phosphates where the alkyl group is even-numbered in the range C8-C18 and the salts have a fluorine content of 52.4 percent to 54.4 percent as determined on a solids basis;
2. Pentanoic acid, 4,4-bis [(gamma-omega-perfluoro-C8-20-alkyl)thio] derivatives, compounds with diethanolamine (CAS Reg. No. 71608-61-2); and

3. Perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis([gamma], [omega]-perfluoro C4-20 alkylthio) methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide.

## II. Amendment of §176.170

In accordance with procedures specified in § 171.130 (21 CFR 171.130) for amending or revoking a food additive regulation, the petition asks us to amend § 176.170 so that it would no longer provide for the use of three perfluoroalkyl ethyl containing FCSs as oil and water repellants for paper and paperboard for use in contact with aqueous and fatty foods. If we determine that new data are available regarding the toxicity of these FCSs that justify amending § 176.170 so that it would no longer allow their use, we will publish such an amendment of the regulation in the Federal Register, as set forth in § 171.130 and § 171.100 (21 CFR 171.100).

We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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